OPTOMED

510(k): K110986

MAY 16 2011

## 5 510(K) SUMMARY

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| **Date:** | February 25, 2011 |
| **510(k) owner's name:** | Optomed Oy |
| **Address:** | Hallituskatu 13-17 D 96, 90100 Oulu, Finland |
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|---|---|
| **Device name:** | Trade name: Optomed Smartscope M5 EY3, Optomed Smartscope M5 ES1<br>Common/usual name: Digital Ophthalmoscope, Exterior ocular photography module<br>Classification name: camera, ophthalmic, ac-powered (21 CFR 886.1120, Product code: HKI) |
| **Predicate devices:** | 1. Optomed Smartscope M3-1 EY1 digital ophthalmoscope (510(k) number: K092056, Product code: HKI)<br>2. WELCH ALLYN 11810 OPTHALMOSCOPE (510(k) number: K003376, Product code: HLI)<br>3. KOWA GENESIS-D hand-held retinal camera (510(k) number: K080681, Product code: HKI) |

**Device description, Intended use & Effectiveness:**

Indications for use: Optomed Smartscope M5 camera with optics modules EY3 and ES1 is a digital ophthalmoscope intended to capture digital images and video of the fundus of the human eye and surrounding area.

Optomed Smartscope M5 is a hand-held digital ophthalmoscope that together with the optics modules EY3 and ES1 is used to capture digital images and video of fundus and surrounding area of the human eye. M5 EY3 has an LED light source with visible white light and infrared light. M5 ES1 has an LED light source with white light and cobalt blue light. Image data is stored on the Flash memory card using 5 megapixel CMOS sensor and transferred to the PC by using USB connection. Device has rechargeable batteries. Table 5-1 below includes a summary of the technical information used in the substantial equivalence discussion.

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**Table 5-1.** Summary of the technical information used in the substantial equivalence discussion.

| Point of comparison | Optomed Smartscope M5 with EY3 and ES1 | Optomed Smartscope M3-1 EY1 | KOWA GENESIS-D | WELCH ALLYN 11800 OPTHALMOSCOPE |
|---|---|---|---|---|
| Indications of use | Optomed Smartscope M5 camera with optics modules EY3 and ES1 is a digital ophthalmoscope intended to capture digital images and video of the fundus of the human eye and surrounding area. | to capture digital images and video of fundus of the human eye. | to capture and save fundus images with mydriatic | to be used to examine the cornea, aqueous, lens, vitreous, and retina of the eye. It has the same operating principles and intended use as many competitive ophthalmoscopes already in commercial distribution. |
| Usage | Prescription use | Prescription use | Prescription use | Prescription use. Trained personnel within medical or school environment. |
| Use condition | Intended to use without mydriatic but can be used also with mydriatic | With or without mydriatic. | With mydriatic. | With or without mydriatic. |
| Observation light source | Visible and infrared LED. EY3 LEDs: White: LWW5SM-KY-QK. NIR: SFH4232 (bin DA) ES1 LEDs: White : Osram Advanced Power Topled LW G6SP-EAFA-JKQL-1 Blue : Osram Advanced Power Topled LB G6SP-V2BB-35-1 | Visible LED | Visible LED 4 VA (approx. 1 W) | Halogen HPX lamp, visible light |
| Observation and display system | 2.4" active matrix color TFT LCD | 2.5" active matrix color TFT LCD | Visual observation | Visual observation |
| Photographing light source | Visible and infrared LED | Visible LED | Xenon flash lamp | - |

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| Camera specification | Color CMOS camera maximum resolution 5Mp. ES1 uses maximum resolution. EY3 uses 2,76 Mp. | Color CMOS camera 6,6Mp. EY1 uses 0,8Mp. | Color CCD camera 2,000,000 pixels | - |
| Dioptre compensation (patient) | at least -20 D to +20 D | at least – 20 D to + 20 D | -15 D ~ +35 D | -20 D to + 20 D |
| Apertures | - | - | Multiple | Multiple |
| Picture angle | Over 40 degrees | At least 25 degree | Horizontal 30 degree Vertical 25 degree | 25 degree |
| Storage media | Flash memory card | Flash memory card | Flash memory card | - |
| Image data format | JPEG, MPEG-1, MPEG-4 | JPEG, MPEG-4 | JPEG and uncompressed format | - |
| Weight | Camera: 400g, EY3: 180G, ES1: 80g | Whole system: 0,6 kg | Camera unit: 1 kg | Ophthalmoscope with handle 0,35 kg |
| Power consumption | Re-chargeable Ni-MH Battery 4.8V; Charging unit 44 VA | Re-chargeable Ni-MH Battery 4.8V; Charging unit 44 VA | 60 VA | Re-chargeable battery handle 3.5 V |
| Output terminals and data collection | USB (1.1) terminal (B-connector). Compatible with Windows® XP/VISTA/7. | USB (1.1) terminal (B-connector). Compatible with Windows® XP/VISTA. | USB (1.1) terminal (B-connector). Compatible with Windows® ME/2000/XP. Foot switch connection cable terminal. | - |
| Exposure parameters | Class 1 LED according to IEC 60825-1:2001 Group 1 instrument according to ISO 15004-2:2007 | Class 1 LED according to IEC 60825-1:2001 Group 1 instrument according to ISO 15004-2:2007 | LED is classified according to IEC 60825-1:1993+A1+A2 | |
| Maximum temperature of parts | Look at discussion | | | |
| Flammability of materials | Look at discussion | | | |
| Brightness controls | Look at discussion | | | |

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| Standards | IEC 60601-1:1988+A1+A2 IEC 60601-1-2:2001+A1 IEC 60601-1-4:2000 EN (IEC) 60825-1:2001 +A1:2002+A2:2001 ISO 15004-2:2007 | IEC 60601-1:1988+A1+A2 IEC 60601-1-2:2001+A1 IEC 60601-1-4:2000 EN (IEC) 60825-1:2001 +A1:2002+A2:2001 ISO 15004-2:2007 | 60601-1:1988+A1+A2 IEC 60825-1:1993+A1+A2 | EN60601-1 IEC 60601-1-2 CAN/CSA-C22.2 No. 601.1-M90 UL 2601-1, Second Edition, 1997 |
| Method of operation | Look at discussion | | | |
| Image quality discussion | Look at discussion | | | |

Technical Information was gathered by side-by-side comparison and labeling of the devices. Optomed Smartscope M5 with optics modules EY3 and ES1 and its predicates were also evaluated by Optomed development team and practicing physicians throughout the product development. Outcome of the evaluation is that ease-of-use and effectiveness of the Optomed Smartscope M5 with optics modules EY3 and ES1 is equivalent or better as its predicates.

Following laboratory bench tests demonstrate Optical radiation safety of the Optomed Smartscope M5 with EY3 and ES1:

1. Optical radiation hazards as defined by standard ISO 15004-2, Ophthalmic instruments -- Fundamental requirements and test methods -- Part 2: Light hazard protection, First edition 2007-02-15.
2. Maximum photometric luminance
3. the optical radiation hazards as defined by ISO 15004 for:
   (i) ultraviolet and infrared radiation, and
   (ii) visible light and near IR radiation (blue-light weighted radiance and aphakic weighted radiance).

The maximum exposure has been demonstrated to be well below the accepted threshold limits for Group 1 devices set out in ISO 15004-2:2007 (see Attachment in Section 9 of the submittal). This is the basis for substantial equivalence related to safety.

The following comparisons of features between subject device and predicate devices provides basis for substantial equivalence related to effectiveness.

Optomed Smartscope M3-1 camera is a predecessor of Smartscope M5 camera, and EY1 eye optics is a predecessor of EY3 eye optics. The improvements in M5 camera with EY3 optics compared to M3-1 camera with EY1 optics are:

- Infrared light for image targeting and capturing
- Autofocus functionality with 3 different shooting modes
- Improved image quality due to
  - New sensor with lower noise

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  - Image pixel resolution is increased
  - Optics efficiency is increased resulting in lower integration time. With lower integration time it is easier to achieve images with less motion blur.
- No visible back reflection in retinal images

When Optomed Smartscope M5 with EY3 and ES1 optics modules is compared to the Kowa Genesis-D, it can be seen that both devices have similar indications for use, and multiple similar technological features. Similar features are:

- Digital image capture method using image sensor. Kowa Genesis-D has a CCD sensor and Optomed Smartscope M5 has a CMOS sensor. Both types of sensors accomplish a same task of capturing light and converting it into electrical signals.
- Both devices store images to a flash memory card and have connectivity towards PC using an USB 1.1 interface.
- Both devices have connectivity to the Microsoft Windows® XP. In addition, Optomed Smartscope has connectivity to the Microsoft Vista® and Windows 7®. Kowa Genesis-D connects also to the Windows ME and Windows 2000. Optomed believes that lack of connectivity to the Windows ME and 2000 does not raise considerations related to the safety and effectiveness when Smartscope is compared to the Genesis-D. Reasoning for this is that both Windows ME and 2000 have mostly been superseded by newer Microsoft operating systems and Smartscope's manuals clearly identify the supported operating systems.
- Both devices have a LED for illumination. In addition, Kowa Genesis has a Xenon flash lamp for photographic illumination.
- Devices have similar method of operation from a user's point of view. Both devices have a graphical user interface and keypad that is used for making adjustments before and during examination and fundus image capture. One obvious difference between devices is that Smartscope does not have a direct visual observation that Genesis-D has. Optomed believes that this technological difference does not raise concerns related to the device safety and effectiveness because from the user's point of view, it does not make a difference, whether target area is studied directly, or from a color TFT display that displays a live image.
- Both Smartscope M5 with EY3 optics module and Kowa Genesis-D store images in a JPEG format. In addition to this, Genesis-D stores uncompressed RAW files and Smartscope stores MPEG-4 videos.
- Smartscope M5 with ES1 optics module is intented for taking images and video of the surface of the eye and surrounding areas while Kowa Genesis-D does not have suitable functionality for examining these parts of the eye.

When Optomed Smartscope M5 with EY3 and ES1 optics modules is compared to the Welch Allyn series 118 Ophthalmoscope, it can be seen that both devices have similar indications for use, and multiple similar technological features. Similar features are:

- Optical Equivalency and Radiation Safety measurements indicate that Optomed Smartscope M5 with EY3 and ES1 is at least safe as Welch Allyn series 118 Ophthalmoscope although these devices have different illumination sources. Smartscope has a LED illumination and Welch Allyn Series 118 Ophthalmoscope has a halogen lamp.

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- Both devices can be used without mydriatic and field of views are similar.
- Both devices are battery powered and batteries are re-chargeable.
- Viewing path and materials used are somewhat similar in both of the devices. Optomed Smartscope M5 with EY3 does not have apertures or different illumination spot sizes as PanOptic 11810 does have. The advantage of the digital imaging is that user of the device can later observe digital images on a computer screen and thus filters or different spot sizes are not needed in order to get best possible outlook of the details of the retina.
- Both devices have a mechanism for refractive error compensation for patient's eye. Smartscope has autofocus functionality and it is also possible to adjust focus by hand using keypad of the device.
- Both devices can be used for examining the exterior parts of the eye and both have a blue illumination source in addition to white light.

To conclude the comparisons above Optomed Smartscope M5 with EY3 and ES1:

- has easier usability than predicate device M3-1 EY1 with addition of IR aiming and autofocus function
- has better picture quality due to better pixel resolution and no back reflection when compared to predicate device M3-1 EY1
- has improved user experience due to non-mydriatic imaging compared to predicate device Kowa Genesis-D
- has better connectivity to newer operating systems than predicate device Kowa Genesis-D
- increased user experience and ease of use compared to Welch Allyn PanOptic due to autofocus functionality

Based on these comparisons the subject device is substantially equivalent to predicate devices regarding effectiveness.

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Public Health Service

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Optomed OY
c/o Mr. Jeffrey D. Rongero
Senior Project Engineer, UL Health Sciences
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle, NC 27709

MAY 16 2011

Re: K110986
Trade/Device Name: Optomed Smartscope M5 EY3 and ES1
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: II
Product Codes: HKI
Dated: April 7, 2011
Received: April 8, 2011

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## 4. INDICATIONS FOR USE

**510(k) Number (if known):** K110986

**Device Name**: Optomed Smartscope M5 with ophthalmoscopic module EY3 and exterior ophthalmic module ES1

**Indications for Use:** Optomed Smartscope M5 camera with optics modules EY3 and ES1 is a digital ophthalmoscope intended to capture digital images and video of the fundus of the human eye and surrounding area.

**Prescription Use** ___X___ **AND/OR** **Over-The-Counter Use** _____
**(Part 21 CFR 801 Subpart D)** **(21 CFR 801 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices



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